

**RULES
OF
THE DEPARTMENT OF HEALTH
AIDS PROGRAM DIVISION**

**CHAPTER 1200-14-2
HIV DRUG REIMBURSEMENT (HDR) PROGRAM RULES**

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1200-14-2-.01 DEFINITIONS.

- (1) For the purpose of these regulations the terms used herein are defined as follows:
- (a) ALPHA INTERFERON - An FDA approved drug also known by the brand names *Intron-A* or *Roferon*.
 - (b) AEROSOLIZED PENTAMIDINE - A formulation of the FDA approved drug Pentamidine isethionate, also known by the brand name *Nebupent*.
 - (c) AIDS - Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome.
 - (d) AZT - The drug Azidothymidine, also known by the generic name "zidovudine" and the brand name *Retrovir*.
 - (e) CERTIFICATION - The determination that an eligible applicant shall become an approved recipient of the HDR program.
 - (f) COMMISSIONER - The Commissioner of the Tennessee Department of Health or his designee.
 - (g) DEPARTMENT - The Tennessee Department of Health
 - (h) ELIGIBLE APPLICANT - An applicant who has an income that does not exceed the maximum monthly income level established by the program (reference paragraph 3, section 1200-14-2-.02), has liquid resources that do not exceed \$8,000 and who has no other source to pay for the drug(s) prescribed under the program.
 - (i) FDA - The U.S. Food and Drug Administration.
 - (j) HDR PROGRAM - HIV Drug Reimbursement Program.
 - (k) HDR PROGRAM APPLICATION - A form available from the Tennessee Department of Health that provides for : 1) a physician's declaration of medical appropriateness for an applicant to receive the drug and the physician's intent to medically follow the applicant; and 2) an applicant's declaration that they meet all eligibility criteria to participate in the HDR program.
 - (l) HIV - Human Immunodeficiency Virus.

(Rule 1200-14-2-.01, continued)

- (m) HIV DISEASE - The state of being infected with the Human Immunodeficiency Virus.
- (n) HIV DRUG REIMBURSEMENT PROGRAM - A program of the Tennessee Department of Health, Bureau of Health Services, to provide drugs specifically approved for HIV disease to certain eligible applicants. Also referred to as the "HDR program" or as the "program".
- (o) MEDICAID - The State Medicaid Program of the Tennessee Department of Health.

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.

1200-14-2-.02 PURPOSE AND ADMINISTRATION OF THE HIV DRUG REIMBURSEMENT (HDR) PROGRAM.

The purpose of the HDR program is to pay for the cost of certain life-sustaining and infection-preventing drugs for low-income Tennessee residents with HIV disease who have no other method of procuring the drug(s). The drugs covered by the state program shall be chosen from among those authorized in the federally funded HDR program and must have FDA approval for specific use in HIV disease. Drugs currently approved under the federal program include AZT, aerosolized pentamidine and Alpha interferon. Additional drugs may be considered for the state program as they are authorized under the federal HDR program. The determining criteria for including an authorized drug in the state program shall include relative demand and cost of the drug, available funds and distribution requirements. The decision to add or delete a drug from the program shall be made jointly by the AIDS Program Director, the Medical Director, and the HDR program administrator. Funds shall be used to purchase drugs at the lowest possible cost under state contracts to fill valid prescriptions for recipients enrolled in the program. Departmental resources shall be utilized for storage, accountability and distribution.

All aspects of the recipient's use of the drug(s) including dosage, directions, temporary or permanent withdrawal, etc. shall be under the direction of the recipient's physician who jointly signs the program application.

Income eligibility will be determined based upon a client's income at 300% of the current year's Federal Poverty Level.

In addition to monthly income limitations, applicants must have less than \$8,000 in liquid resources, must not have third party prescription coverage for the drug, and must not be authorized to receive Medicaid benefits.

The program shall develop and distribute applications and instructional forms. Current maximum income levels, specific drugs covered by the program and other guidelines for participation shall be published and made available to applicants, interested physicians, and other inquiring parties. The program shall require applicants and their attending physicians to complete and sign applications which state that they understand and meet all eligibility criteria for the program. In addition, the program shall incorporate procedures to provide drug inventory control from time of purchase to the filling of a legal prescription for an authorized program recipient. The program shall coordinate with Medicaid to ensure that persons shall not receive benefits from both programs simultaneously.

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Amendment filed December 29, 1995; effective April 29, 1996.

*Example of monthly income level criteria for a single adult without dependents applying for *Retrovir* coverage under the program: If the current average out-of-pocket cost for a month's supply of *Retrovir* was \$800.00 and the current Federal Poverty Income Standard was \$480.00, then, the current maximum allowable monthly income for a program participant would be \$1280.00.

1200-14-2-.03 PROGRAM LIMITED TO AVAILABLE FUNDS.

The reimbursement for drugs by the HDR Program shall be limited by the availability of funds appropriated by the Tennessee General Assembly specifically for that purpose.

The approval of new applications shall cease if funding is not available to provide new recipients at least a six-month supply of drug(s). Applications meeting eligibility criteria but denied due to funding shortage shall be retained for reconsideration when funding becomes available. Priority for funding shall be given to recipients already in the program. Priority among pending applications shall be based upon the date received in the program office.

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.

1200-14-2-.04 ELIGIBILITY CRITERIA.

- (1) To be deemed eligible for coverage by the HDR program a recipient must meet all of the following criteria:
 - (a) meet the medical criteria established by generally accepted and proven treatment standards for HIV disease, including standards derived from published drug trials and recommendations of federal agencies;
 - (b) have been prescribed the drug(s) by a physician licensed in Tennessee;
 - (c) have a signed statement from the prescribing physician indicating the physician's intent to medically follow the applicant and monitor the intake and potential side effects of the drug(s);
 - (d) declare that they are not receiving and are not authorized to receive Medicaid benefits;
 - (e) meet the program's financial and resource criteria;
 - (f) not be covered by any other source of third-party reimbursement for the prescribed drug(s);
 - (g) submit a completed and signed HDR program application form.

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.

1200-14-2-.05 DEEMING OF INCOME AND RESOURCES.

- (1) **ADULTS:** for the purpose of eligibility determination for an applicant 18 years of age or older, only the income and resources of the applicant and the applicant's legal spouse with whom the applicant resides shall be used in the HDR program eligibility determination
- (2) **MINORS:** for the purpose of eligibility determination for an applicant under the age of 18, the income and resources of the applicant and the income and resources of the legal parent or parents with whom the applicant resides shall be used in the HDR program eligibility determination. Income and resources of stepparents and legal guardians shall not be used in the HDR program eligibility determination.

(Rule 1200-14-2-.05, continued)

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.

1200-14-2-.06 CERTIFICATION OF COVERAGE BY PROGRAM.

Upon approval of an application, the recipient shall be notified in writing of their certification to receive coverage by the HDR program. The recipient shall additionally be informed that the benefit coverage shall continue for a minimum of 6 months, or until the person gains Medicaid benefits, or until the end of the federal fiscal year during which the person was certified; whichever comes first. The applicant shall be further informed that assurance of coverage shall not extend beyond the current federal fiscal year.

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.

1200-14-2-.07 CONFIDENTIALITY OF RECORDS.

All applicant or recipient identifying information or records of the HDR program shall be considered confidential as required by the federal legislation authorizing funding assistance to the program. Such information or records shall not be disclosed by the program except for those purposes for which a signed release is provided by the person served. All correspondence containing the identity of program applicants or recipients shall be sealed and marked "CONFIDENTIAL".

Authority: T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.